



Australian Government

Department of Health
Therapeutic Goods Administration

Quality Management System Certificate ISO 13485:2003

Issued to:

Haemologic Biotech Pty Ltd

This is to certify that the Quality Management System for the design, development and manufacture of the devices described below conforms to the relevant provisions of ISO13485:2003.

TGA File Number: 2014/028697

Manufacturer Name: Haemologic Biotech Pty Ltd

Manufacturer Address: D2 & D3 / 15 Narabang Way
BELROSE NSW 2085
AUSTRALIA

Scope of Certification: The design, development and manufacture of Blood collection, Cell culture container, Tubing (nebuliser set, low pressure compressed gas and arthroscopy irrigating), Air/oxygen masks and accessories, Non heated nebuliser, Syringes (including self-loading) and IV Infusion tubing set products.

Special Conditions: Nil

Effective Date: 30 November 2017

Expiry Date: 3 February 2019

This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.

Signature

30th Nov 2017

Date

Keith Smith
Senior Adviser
Quality Audits and Assessments Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: +61 (0)2 6221 6868

MI-2016-CE-01697-1

This Certificate is the property of the Medical Devices Branch, TGA, and must be returned upon demand.